REMARKS

Claims 1-9 and 12-15 are pending, of which claims 6-9 and 12-13 are withdrawn as directed to non-elected subject matter. Claims 1-5 and 14-15 are presently under consideration.

Claims 1 and 4 have been amended to clarify the claimed invention by specifying that the food or pharmaceutical preparation is administered to a bird or a mammal "in need thereof". No new matter has been added.

Applicant's Summary of Interview

A telephonic interview was held on May 11, 2011. Attending the interview were Examiner Paul Dickinson and Applicant's representatives Charles L. Gagnebin, III and Lin J. Hymel. The rejections in the Final Office Action dated January 31, 2011 were discussed. Case law and possible amendments to the claims relevant to overcoming the rejections were discussed.

Rejection Under 35 U.S.C. § 102

Claims 1 and 4 stand rejected as being anticipated by US 6239297 (Takesako et al.). The rejection is respectfully traversed.

This rejection is maintained from the previous office action. The Examiner has argued that the intestinal flora of a given person is regularly out of balance, and that the patient population of the Takesako '297 patent would inherently comprise members whose intestinal flora is out of balance. The Examiner has also referenced the *Atlas Powder* case for the principle that a new use or unknown property of an old composition does not render the composition patentable.

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290
FAX. (617) 451-0313

In order to further clarify the subject population for treatment according to claims 1 and 4, the claims have been amended to specify in the preamble the condition to be treated (a bird or mammal whose intestinal flora is out of balance) and to specify that the step of administering is carried out for a bird or mammal "in need thereof". The present claims as amended make clear that the subject population, i.e., birds and mammals in need of treatment for an intestinal flora that is out of balance, is different from the subject population in the Takesako '297 patent, which are humans in need of an antifungal agent or an immunosuppressant agent. The present situation is analogous to *Jansen v. Rexall Sundown, Inc.*, 342 F3d 1329 (Fed. Cir. 2003), where the court ruled that a preamble describing a set of patients (in need of preventing pernicious anemia by vitamin administration) is given life and meaning by reference to a subject "in need thereof" in the step of administering. It is noted that the Examiner's reference to *Atlas Powder* is off point, as the present claims are directed to methods and not compositions. Thus, under the Federal Circuit's ruling in *Jansen*, present claims 1 and 4 are not anticipated by the Takesako '297 patent because the subject population in that reference was different than in the present claims.

The withdrawal of the rejection is respectfully requested.

Claims 1-5 stand rejected as being allegedly anticipated under 35 U.S.C. 102(a) by JP 2003-252765 (machine translation). The rejection is respectfully traversed.

Attached hereto is a certified English translation of the Dutch language priority document, Dutch Application No. 1022443,

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290
FAX. (617) 451-0313

filed January 20, 2003. This perfects Applicant's claim to the priority date of the '443 application, which predates the publication date of JP 2003-252765 (September 10, 2003). Therefore, JP 2003-252765 does not qualify as prior art to the present application, and the rejection should be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 1-5 and 14-15 stand rejected as allegedly obvious over US 6610835 (Liotta et al.). This rejection also has been maintained from the previous office action. The rejection is respectfully traversed.

The '835 patent describes the use of certain sphingolipids as suppressors of carcinogenesis, and suggests their administration in order to prevent certain conditions, such as colon cancer. However, the '835 patent completely fails to teach or even suggest the oral administration of sphingolipids to the group of subjects specified in the present claims, which is a bird or a mammal whose intestinal flora is out of balance. There is no suggestion of such a group of subjects, or of the treatment of such a medical condition, in the '835 patent. For this reason alone, '835 does not render the claims obvious.

Moreover, the method described in the '835 patent does not involve the use of orally administered sphingolipids, either in a food or a pharmaceutical preparation. Instead, the '835 method requires the use of prodrugs of sphingolipids (i.e., chemically modified sphingolipids that are converted to sphingolipids in the body. The reason for using prodrugs rather than sphingolipids themselves is to increase their survival in the lower GI tract and thereby increase their bioavailability. See, e.g., '835 at col.

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GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290
FAX. (617) 451-0313

9, lines 37-40. The '835 patent teaches that unprotected sphingolipids are cleaved in the intestine, so that only a small amount of orally administered sphingolipid reaches the lower intestine. Therefore, '835 teaches away from the oral administration of sphingolipids, and teaches away from the method of the instant claims. Further, based on the disclosure of Liotta '835, the ordinary skilled person would not have had a reasonable expectation of success in treating an out-of-order intestinal flora in a bird or mammal using oral administration of a sphingolipid, because '835 states that little orally administered sphingolipid survives to reach the lower intestine.

Therefore, the present claims are not obvious over the '835 patent because '835 does not teach the required subject group or medical condition, teaches away from oral administration of sphingolipids, and fails to provide any reasonable expectation of success for the claimed method. The withdrawal of the rejection is respectfully requested.

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
TEL. (617) 542-2290
FAX. (617) 451-0313

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

Willem Ferdinand Nieuwenhuizen

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By:/Charles L. Gagnebin iii/
Charles L. Gagnebin III
Registration No. 25,467
Attorney for Applicant(s)
bgagnebin@wsglip.com

WEINGARTEN, SCHURGIN,
GAGNEBIN & LEBOVICI LLP
Ten Post Office Square
Boston, MA 02109
Telephone: (617) 542-2290
Telecopier: (617) 451-0313

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